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1

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/025,350	12/18/2001	Michael N. Pollak	28758.57	4785

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Diagnostic Systems Loboatories Inc.
Attn In House counsel
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Webster, TX 77598

EXAMINER

HOLLERAN, ANNE L

ART UNIT	PAPER NUMBER
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1643

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/025,350	Applicant(s) POLLAK ET AL.	
	Examiner Anne L. Holleran	Art Unit 1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 April 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/06</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The amendment filed 4/19/2007 is acknowledged. Claim 27 was canceled.
2. Claims 21-26 are pending and examined on the merits.

Claim Rejections Maintained and New Grounds of Rejection:

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 21-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 21 and 24 are indefinite because of the phrase “reporting an increased risk for prostate cancer in the healthy individual”.

The specification does not contain a description of methods that comprise a “reporting” step, and does not define the scope of activities that are included. Is “reporting” limited to informing a second individual of increased risk for prostate cancer? Can someone “report” to themselves? In other words, does this step read on drawing a conclusion?

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 21-26 remain rejected under 35 U.S.C. 102(b) as being anticipated either by Juul-A (Juul, A. et al. J. Clin. Endocrinol. Metab., 78(3): 744-752, 1994) or by Juul-B (Juul, A. et al., Clinical Endocrinology, 41: 85-93, 1994; cited in IDS).

Applicant's arguments have been carefully considered, but fail to persuade. Applicant's traverse of the rejection consists of stating that the claims recite the step of reporting an increase risk of prostate cancer in a healthy individual, wherein an elevated concentration of IGF-I above the reference level indicates an increased risk for prostate cancer, pointing out that neither Juul-A nor Juul-B teach that increase IGF-I levels are associated with an increased risk for prostate cancer, and that neither Juul-A nor Juul-B teaches the reporting of an increased risk of prostate cancer in a healthy individual. Applicant concludes that neither Juul-A nor Juul-B teaches each and every element of claims, and therefore do not anticipate the claims.

However, the "reporting" step does not appear to be an actual manipulative step, but instead appears to be a recitation of mental activity. The specification does not contain a definition of what is encompassed by a "reporting" step. Therefore, "reporting an increase risk for prostate cancer in the healthy individual" may be broadly interpreted to include a step of "concluding" that a healthy individual had an increased risk for prostate cancer. Also, the claim

Art Unit: 1643

does not recite the conditions that lead to the performance of the reporting step, because the wherein clause relates to the claim's preamble, and not to the reporting step.

Thus, the claims, even as amended, do not appear to be materially different from the methods described in the prior art in the recitation, because it is interpreted as a method comprising two active steps, that of measuring the concentration of IGF-I in a body fluid from a healthy individual outside a reference group of healthy individuals and comparing the concentration of IGF-I in the healthy individual outside the reference group to a reference level. of the two active steps. Because the preamble to the claims does not result in any manipulative difference between the claimed methods and the prior art methods, the preamble is not considered a limitation. Therefore, Juul-A or Juul-B teach the claimed methods even though Juul-A or Juul-B fail to teach that an increase in IGF-I levels are associated with an increased risk for prostate cancer.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

Art Unit: 1643

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 21-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mantzoros (Mantzoros et al, British Journal of Cancer 76(9): 1115-1118, 1997; of record).

Claims 21-26 are interpreted as encompassing methods of predicting an increase risk for prostate cancer comprising measuring the concentration of IGF-I in a body fluid from a healthy individual outside a reference group and comparing the concentration of IGF-I in the healthy individual outside the reference group to a reference level of IGF-I concentration in a body fluid, where the reference level of IGF-I concentration is the level measured in the reference group, where the reference group is a group of healthy individuals that do not have prostate cancer.

Mantzoros teaches that IGF-I levels in prostate cancer patients are higher than IGF-I levels in men that do not have prostate cancer, and Mantzoros concludes that increases levels of IGF-I is a risk factor for prostate cancer (see abstract). Mantzoros fails to measure IGF-I levels in healthy individuals not yet diagnosed with prostate cancer, but does measure IGF-I levels in

Art Unit: 1643

patients with benign prostatic hyperplasia (BPH). However, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have used the method of Mantzoros to look at the IGF-I levels of healthy individuals at risk for prostate cancer and to compare their IGF-I levels to the IGF-I levels of a reference group and, if an elevation of IGF-I levels was found, to have concluded that the tested individual was one with an increased risk for prostate cancer because the data of Mantzoros indicated that an association between an increased risk of prostate cancer and elevated IGF-I levels existed. One would have had a reasonable expectation of success because the data of Mantzoros indicated that there was a relationship between elevated IGF-I levels and prostate cancer.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne Holleran, whose telephone number is (571) 272-0833. The examiner can normally be reached on Monday through Friday from 9:30 am to 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, can be reached on (571) 272-0832. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform to the notice published in the Official

Art Unit: 1643

Gazette, 1096-OG 30 (November 15, 1989). The Official Fax number for Group 1600 is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).



Anne L. Holleran
Patent Examiner
July 6, 2007

ALANA M. HARRIS, PH.D.
PRIMARY EXAMINER